IMPLANTABLE CARTILAGINOUS TISSUE REPAIR DEVICE

FIELD OF THE INVENTION

[0001] The present invention relates generally to surgical devices for approximating, repairing or regenerating damaged or diseased cartilage, and to manufacturing methods for such devices. In particular, the present invention relates to a device for the replacement, partial replacement or augmentation of damaged cartilage applicable to the repair of articular cartilage, the meniscus of the knee, the tempero-mandibular joint or an intervertebral disc.

BACKGROUND OF THE INVENTION

[0002] Cartilage in the adult mammalian body occurs in three principal forms: hyaline cartilage; white fibrocartilage; and yellow elastic cartilage. Hyaline cartilage is chiefly present as articular cartilage in the synovial diarthroidal joints of the hip and shoulder and between the long bones where it forms the stiff and smooth articulating surfaces. White fibrocartilage is present in the menisci of the knee and temporomandibular joint of the jaw and in the intervertebral discs. Yellow elastic cartilage gives support to the epiglottis, Eustachian tube and external ear.

[0003] Three pathological conditions involving cartilage damage are very common: osteoarthrosis of articular cartilage; injury to the fibrocartilage of the knee menisci and collapse, rupture or herniation of the intervertebral disc.

[0004] Osteoarthrosis is caused by the progressive damage and breakdown of articular cartilage most commonly in the hip and knee and is an important cause of pain and reduced mobility in old people. Injury to the fibrocartilage of the meniscus is a common sports injury and is also seen as a result of road traffic accidents.

[0005] The structure and function of articular cartilage has been reviewed by Hasler E M, Herzog W, Wu J Z, Muller W, Wyss U. 1999 in their article, "Articular cartilage biomechanics: Theoretical models, material properties, and biosynthetic response" published in Critical Reviews In Biomedical Engineering vol 27 part 6 pages 415-488. Articular cartilage is highly specialized to provide a relatively frictionless, highly lubricated, wear resistant surface between relatively rigid bones. It also functions to transmit and distribute the forces arising from loaded contact to the surrounding cartilage and underlying subchondral trabecular bone. Hyaline cartilage is not thought to act as a shock absorber limiting the forces to the bone from impacts. This is because its volume for dissipating energy is very small compared to that of bone and because it actually increases in stiffness with increasing strain rate making it an inappropriate material for use as a shock absorber. Articular cartilage is a non-vascular connective tissue largely composed of a fluid phase consisting principally of water and electrolytes interspersed in a solid phase containing type II collagen, proteo-glycan and other glycoproteins. The latter constituents surround and are secreted by highly specialized mesenchymal cells, the chondrocytes which account for some 10% of the volume of articular cartilage. Healthy articular cartilage is strong and stiff (modulus between 1 and 20 MPa). The arrangement of the collagen fibrils within articular is essential to its function. They are arranged in a complex arcade structure forming columns arranged normal to and anchored in the osteochondral junction. These columns run up through the deep layer of cartilage but the predominant fibre orientation gradually changes to form the arches of the arcade structure in the superficial cartilage.

[0006] In the superficial layer which abuts the joint space, the meshwork of collagen fibrils is much denser while the fibrils are almost entirely tangential to the cartilage surface. The orientation of collagen in articular cartilage is vital to its mechanical function.

[0007] No wholly satisfactory procedure exists for replacing damaged articular cartilage in osteoarthrosis and instead artificial prostheses are most commonly used to replace the entire hip and knee joints. While these increase mobility and reduce pain they suffer from progressive wear, mechanical failure, adverse tissue reactions and loosening at their interphase with the bone.

[0008] The menisci of the knee joint are C-shaped discs interposed between the femoral condyles and tibial plateau and have the function of compressive load spreading, shock absorption, stabilization and secretion of synovial fluid for lubrication. The structure, function and pathology of the menisci have been reviewed by S. M. Bahgia and M. Weinick, Y. Xing, and K. Gupta (2005) Meniscal Injury, E-medicine World Library, 27 Jul. 2005, http://www.emedicine.com/pmr/topic75.htm. The outer rim is vascular while the central part is avascular fibrocartilage. Type I collagen (non-articular cartilage fibrillar collagen) accounts for about 70% to 90% of the collagen of the menisci. Most of the collagen is arranged in rope-like circumferential fibres together with fewer radial tie fibers. As in articular cartilage, collagen orientation is extremely important for the mechanical function and fixation of this structure. Compression of the meniscus leads to tensile hoop loading of the circumferential fibres and radial loading of the radial fibres, resisting spreading and flexing of the menisici. Thus the ability of the meniscus to spread load and dissipate energy is dependent on the integrity of the collagen fibre lay. For this reason damage to these fibres increases the risk of secondary osteoarthrotic damage to the condylar cartilages as the normal load distribution and shock-absorbing functions are impaired. The meniscofemoral ligament firmly attaches the posterior horn of the lateral meniscus to the femoral condyle and the coronary ligament anchors the peripheral meniscal rim to the tibia.

[0009] Meniscal injuries are fairly common in adults and are most frequently sports-related. They are less common in children over 10 years old and rare in children under 10 with morphologically normal menisci (Iobst, C. A. and Stanitski, C. L., 2000, Acute knee injuries. Clin Sports Med. 2000 October; 19 (4):621-35).

[0010] Surgical treatment of damaged menisci is often necessary. Although total or partial meniscectomy was popular some forty years ago, it is now well understood that this procedure leads to articular cartilage degeneration (King, D. Clin. Orthop. 1990, 252, 4-7; Fairbank, T. J. J. Bone Joint Surg. Br. 1948, 30, 664-670). The extent of the degeneration of the cartilage appears to depend on how much tissue has been removed. Therefore partial meniscectomy is the current procedure of choice. However, even with partial mensicectomy, secondary osteoarthrosis is still a long-term consequence. Better alternatives to partial meniscectomy are therefore being sought. Allograft transplantation is a fairly successful alternative. However there is no proof that replacement of the meniscus with an allograft can re-establish some of the important meniscal functions, and thereby prevent or reduce the development of osteoarthrosis secondary to meniscectomy (Messner, K. and Gao, J. 1998 The menisci of the